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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
PORTLAND DIVISION

AMERICAN APPAREL & FOOTWEAR
ASSOCIATION, INC.; HALLOWEEN
INDUSTRY ASSOCIATION, INC.;
JUVENILE PRODUCTS MANUFACTURERS
ASSOCIATION, INC.; THE TOY
ASSOCIATION, INC.; (individually and d/b/a
SAFE TO PLAY COALITION),

Plaintiffs,

v.

PATRICK ALLEN, in his official capacity as
the Director of the Oregon Health Authority;
ELLEN ROSENBLUM, in her official capacity
as Attorney General for the State of Oregon's
Department of Justice,

Defendants.

CASE NO. 3:21-cv-01757

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

Plaintiffs American Apparel & Footwear Association, Inc., Halloween Industry Association, Inc., Juvenile Products Manufacturers Association, Inc., The Toy Association, Inc., and the Safe to Play Coalition (collectively, "Plaintiffs"), assert the following claims against Defendants Patrick Allen, in his official capacity as the Director of the Oregon Health Authority, and Ellen

Rosenblum, in her official capacity as Attorney General for the State of Oregon’s Department of Justice, and allege:

NATURE OF ACTION

1. Plaintiffs bring this action for a declaration that two provisions of Oregon’s Toxic-Free Kids Act are preempted by the federal Consumer Product Safety Act and the Federal Hazardous Substances Act. The Oregon legislature passed the Toxic-Free Kids Act in 2015 in order to identify and then “phase out” (that is, ban) a long list of chemicals from certain children’s products sold in Oregon. Oregon cannot ban these chemicals (what it calls high priority chemicals of concern for children’s health, or HPCCCHs) from children’s products that are allowed under federal law because federal law expressly preempts Oregon’s non-“identical” laws and implementing regulations.

2. The first provision at issue in this lawsuit (OAR 333-016-3015¹) requires onerous fees and testing to request an “exemption” from being banned under Oregon law *that already exists* solely because of the fact of conflicting federal law. Oregon’s administrative rule disregards this automatic operation of federal law to preempt non-“identical” Oregon law, attempting instead to compel manufacturers to submit a “request” — with onerous supplementary information not required under federal law — that Oregon not ban chemicals that Oregon cannot ban in the first place because they are permitted in children’s products by federal law. Because federal preemption does not depend on a state-required “request” to recognize that preemption, Oregon’s attempt to ban HPCCCHs from children’s product without this request cannot prevail.

3. The other two preempted provisions at issue in this lawsuit (ORS 431A.258 and its implementing administrative rule, OAR 333-016-2060) require the identification and reporting of chemicals even though, as present in a children’s toy, they present no risk of harm to children. After three such reports (under biennial notices to the Oregon Health Authority), the Toxic-Free

¹ Even though OAR 333-016-3015 is merely the “implementing” administrative rule enacted by the Oregon Health Authority for ORS 431A.260, the offending provision preempted by federal law is found only in the administrative rule, not its statutory authority.

Kids Act purports to require the “removal or substitution” of HPCCCHs from the children’s product — again, without regard to federal law permitting the sale of these same products with those chemicals. Oregon’s provisions are preempted by federal law because federal law bans the sale of children’s products only where a chemical, including the HPCCCHs from Oregon’s list, is “accessible” to a child, which means that it presents an actual hazard to that child in some way.

4. Plaintiffs seek a declaration that federal law preempts these provisions and an order permanently prohibiting enforcement of these provisions.

PARTIES

5. Plaintiff American Apparel & Footwear Association, Inc. (AAFA), is a not-for-profit corporation. AAFA represents more than 1,000 brands as the trusted public-policy and political voice of the apparel and footwear industry with more than 3 million workers and more than \$350 billion in annual U.S. retail sales, of which approximately \$30 billion are attributed to children’s products.

6. Plaintiff Halloween Industry Association, Inc. is a not-for-profit corporation that represents businesses involved in the manufacture, importation or distribution of Halloween products including costumes, decor, novelty items and party supplies. The Halloween Industry Association has grown to become the preeminent authority on Halloween and serves as a non-profit voice of the industry.

7. Plaintiff Juvenile Products Manufacturers Association, Inc. is a not-for-profit corporation organized under the laws of New York that represents businesses involved in creating children’s products used to care for and protect children from before birth through preschool. Juvenile Products Manufacturers Association’s more than 250 members include manufacturers, importers, laboratories and distributors of juvenile products, and its members account for almost 90% of all sales of such products in the United States. Juvenile Products Manufacturers Association’s mission is to be a leading force in the growth and health of the juvenile products industry, including advocating for public policies and laws that promote the health, care and well-being of babies.

8. Plaintiff The Toy Association, Inc. is a not-for-profit corporation that serves as a unifying force for members' creativity, responsibility, and global success, advocating for their needs and championing the benefits of play. The Toy Association is committed to serving as the toy community's voice on the cognitive, social, emotional, and creative benefits of play, while providing members with programs, events, services, and tools that will help them to deliver safe, fun and developmentally beneficial toys and games to children around the world. The Toy Association has a dedicated team leading the industry's safety initiatives, including fulfilling the role of chair in the ongoing review process for the ASTM F963 Toy Safety Standard, and educating manufacturers on safety and quality standards. The Toy Association serves as the voice of toy manufacturers with regulators in the U.S. and internationally.

9. Plaintiffs are members of the Safe To Play Coalition, which is a coalition of trade associations representing makers of apparel, toys, crafts, juvenile products, and Halloween items that are subject to extensive federal regulation.

10. Plaintiffs bring this suit on behalf of their members, which sell toys, apparel, child-care products, and other safe children's products in Oregon in full compliance with federal and state law regulating chemical and other potential hazards found in children's toys.

11. Defendant Patrick Allen, who is sued in his official capacity as the Director of the Oregon Health Authority, is an individual residing in Oregon.

12. Defendant Ellen Rosenblum, who is sued in her official capacity as Attorney General for the State of Oregon's Department of Justice, is an individual residing in Oregon.

JURISDICTION AND VENUE

13. This Court has jurisdiction over this cause of action under 28 U.S.C. § 1331, in that this cause of action arises under the Constitution and/or laws of the United States, and, specifically, under Article VI, Clause 2 of the United States Constitution, commonly known as the Supremacy Clause.

14. Declaratory relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202 because an actual controversy exists regarding whether provisions of the Oregon’s Toxic-Free Kids Act and related administrative rules are preempted by federal law.

15. Under *Ex Parte Young*, 209 U.S. 123 (1908), actions against state officials seeking prospective injunctive relief are not barred by sovereign immunity.

16. Venue is proper in this Court under U.S.C. § 1391(b) because Defendant resides in this District and a substantial part of the events or omissions giving rise to the claim occurred in this District.

FACTUAL ALLEGATIONS

17. For over 60 years, a comprehensive federal statutory scheme has governed the sale of consumer products containing potentially toxic chemicals, including children’s toys.

18. In 1960, Congress enacted the Federal Hazardous Substances Act (“FHSA”), 15 U.S.C. § 1261 *et seq.*, in response to mounting evidence of the risks, particularly to children, of hazardous household products.

19. The FHSA regulates consumer products intended for use or packaged in a form suitable for use in the household or by children, and it defines “toxic” to mean a substance that “has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.” *Id.* § 1261(g).

20. Section 2(f) of the FHSA defines a “hazardous substance” to mean any “substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.” *Id.* at § 1261(f)(1)(A).

21. Twelve years after enactment of the FHSA, Congress enacted the Consumer Product Safety Act (“CPSA”), 15 U.S.C. § 2051 *et seq.*, which established the Consumer Product Safety Commission (the “CPSC”).

22. Congress found that “control by State and local governments of unreasonable risks of injury associated with consumer products is inadequate and may be burdensome to manufacturers.” *Id.* § 2051(a)(4). Accordingly, Congress created the CPSC “to develop uniform safety standards for consumer products to minimize conflicting State and local regulations.” *Id.* § 2051(b)(3).

23. And in the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), Congress added substantial testing and certification requirements for children’s products, further restricted lead in these products, and adopted ASTM F963 as a mandatory Toy Safety Standard with added additional limits on heavy metals and phthalates in toys and defined childcare articles. 15 U.S.C. § 2056b(a).

24. The CPSA gave the CPSC authority to issue regulations enforcing the FHSA and created a supplemental ban on consumer products not banned by the FHSA where the CPSC finds that those products present an “unreasonable risk of injury.” *Id.* § 2057. “Consumer products” under the CPSC’s jurisdiction are broadly defined. *Id.* § 2052(a)(5). And “children’s products” are specifically defined, which includes the universe of products sought to be regulated by Oregon’s Toxic-Free Kids Act. *Id.* § 2052(a)(2); ORS 431A.253(3)(a).

25. The CPSC implements the FHSA and the CPSA by issuing rules and guidance regulating hazardous substances in consumer products, including children’s toys.

26. The CPSC, which has “primary responsibility for enforcement” of the FHSA and CPSA, *Riegel Textile Corp. v. Celanese Corp.*, 649 F.2d 894, 901 (2d Cir 1981), has fulfilled its legislative mandate by issuing a series of regulations determining when a children’s product is banned because it contains potentially toxic chemicals.

27. The CPSC also issued regulations interpreting and supplementing the statutory definition of “toxic.” 16 CFR § 1500.3(c)(2).

28. The CPSC declared that substances are toxic if, at specified levels, they produce specified injuries within a specified time period in lab rats or rabbits. *Id.* § 1500.3(c)(2)(i).

29. And CPSC declared that a substance is categorically toxic if “it is or contains a known or probable human carcinogen,” “neurotoxin,” or “developmental or reproductive toxicant” that is accessible to children *Id.* § 1500.3(c)(2)(ii).

30. Products containing substances that qualify as toxic under the CPSC’s regulation are automatically banned by the FHSA if they are intended for children, could cause substantial injury or illness through reasonably foreseeable handling or use, including ingestion, and if the substance is susceptible of access to the child.

31. In turn, section 2(q) of the FHSA states that “a toy, or other article intended for use by children” is a “banned hazardous substance” if it “is” a “hazardous substance” as defined in § 1261(f) or if it “bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted.” 15 U.S.C. § 1261(q).

32. If a product is a “banned hazardous substance” under § 2(q), selling that product violates federal law. 15 U.S.C. § 1263. In other words, a toy or product intended for children that is “toxic” under § 1261(g) is a “hazardous substance” under § 1261(f) if it could cause substantial injury or illness as a result of reasonably foreseeable handling or use, and, therefore, is a “banned hazardous substance” under § 1261(q) that cannot be sold in the United States.

33. Toxic chemicals in children’s toys are regulated, in exacting detail, by this federal regime. *See* 16 CFR Part 1500, et. seq. Also, for example, the CPSA sets limits on a range of phthalates (15 U.S.C. § 2057(c); 16 CFR Part 1307; 16 CFR § 1308.1) and the testing method for phthalates (CPSC-CH-C1001-09.4).

34. The toy safety standard issued by the American Society for Testing and Materials (“ASTM”), known as ASTM F963 (15 U.S.C. § 2056b(a)), is a mandatory toy-safety standard under 15 U.S.C. § 2058; 16 CFR § 1250.1 (“This part establishes a consumer product safety standard for toys that mandates provisions of ASTM F963.”). ASTM F963 establishes the precise manner for testing with CPSC accredited laboratories (CPSIA Sec. 108(e); 16 CFR Part 1200) and for certification as compliant with Children’s Product Certifications (15 U.S.C.

§ 2063; 16 CFR Part 1107, 1109 and 1110), with such testing and certification requirements also applicable to all “children’s products” under the CPSA.

35. ASTM F963 also includes and governs other chemicals, such as cadmium and antimony, which Oregon also includes in its list of “high priority chemicals of concern for children’s health.” OAR 333-016-2020. ASTM F963 sets maximum levels of specified toxic chemicals in both the surface coating and “accessible” substrate materials of children’s toys, including certain heavy metals (lead, mercury, antimony, cadmium, and arsenic).

36. ASTM F963 specifies detailed test methods to determine the “accessibility” or “bioavailability” of chemicals to children, and it contains nearly 70 pages of detailed requirements aimed at addressing various possible risks associated with toys, including the risk of exposure to toxic chemicals.

37. To protect this comprehensive federal statutory and regulatory scheme, both the FHSA and the CPSA contain provisions expressly preempting state laws that diverge from federal standards.

38. The FHSA provision provides that if the CPSC issues a regulation to protect against the “risk of illness or injury associated with a hazardous substance” then “no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury *unless such requirement is identical to the requirement established under such regulations.*” PL 94–284 (S 644), PL 94–284, May 11, 1976, 90 Stat 503 (emphasis added).

39. The CPSA’s express preemption is equally unambiguous that federal law fully preempts all contrary state laws, regulations, or standards:

Whenever a consumer product safety standard under this chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, *unless*

such requirements are identical to the requirements of the Federal standard. 15 U.S.C. § 2075 (emphasis added).

40. Despite these federal laws and regulations, the Oregon legislature passed the Oregon Toxic-Free Kids Act in 2015 to identify and, eventually, ban a list of “High Priority Chemicals of Concern for Children’s Health” (“HPCCCH”) found in the very same children’s toys and other products already extensively regulated under federal law. ORS 431A.253 to .280.

41. The Oregon Health Authority, the state agency responsible for enforcement of the Toxic-Free Kids Act, has since promulgated a long list of administrative rules under the authority of the Toxic-Free Kids Act. OAC 333-016-2001 to -3080.

42. The first “phase” of enforcement of the Toxic-Free Kids Act involved OHA’s promulgation of rules to establish the list of HPCCCHs subject to testing, regulation, and banning under Oregon’s new law.

43. The second “phase” of enforcement required toy manufacturers, among other things, to test toys to determine the amount of HPCCCHs in those toys and then report, on a biennial basis beginning on January 1, 2018, the amount of those HPCCCHs found in each toy. The Toxic-Free Kids Act permitted this reporting under an existing, national system already in use by manufacturers for reporting chemicals under similar laws in Washington and other states.

44. The third and final “phase” of enforcement requires the removal or substitution of any HPCCCH reported to OHA for a third time in the biennial notices for three products: children’s cosmetics, any “mouthable” toy, or toys for children under three years old. That third biennial notice, for many toy manufacturers, falls on January 1, 2022.

45. Manufacturers found in violation of the Toxic-Free Kids Act are subject to punishment by civil penalties, including additional penalties for subsequent or ongoing violations. ORS 431A.275; OAR 333-016-3030.

46. Without prospective injunctive relief prohibiting the enforcement of Oregon’s state laws preempted by the FHSA and CPSA, Plaintiffs and their member manufacturers will suffer irreparable harm and lack an adequate remedy at law.

COUNT 1

DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

OAR 333-016-3015

47. Plaintiffs reallege paragraphs 1-46.

48. The Oregon Health Authority drafted OAR 333-016-3015, effective March 1, 2021, to implement ORS 431A.260, which is part of the Toxic-Free Kids Act.

49. ORS 431A.260 requires the “removal or substitution” of certain chemicals from children’s toys, but it also provides that toy manufacturers are “exempt” from this requirement if the toy contains chemicals that are considered safe under the federal Consumer Product Safety Improvement Act (the “CPSIA”).

50. Despite Oregon’s recognition in ORS 431A.260 that federal law, with nothing more, automatically preempts conflicting Oregon law governing chemicals permitted in children’s toys, OAR 333-016-3015 impermissibly adds additional requirements to be considered “exempt” from the operation of Oregon law.

51. These impermissible additional requirements include: (1) payment of a \$1,500 fee, (2) submission of a request for exemption, (3) a citation to the applicable federal statute or safety standard with preemptive effect, (4) supporting documentation showing compliance with those federal statutes or standards, and (5) additional product information (including the product category, brand names and model numbers, and UPC or codes). OAR 333-016-3015(4).

52. These additional burdens are preempted by federal law and are also beyond the powers and authority of the OHA in “implementing” ORS 431A.260.

53. The Oregon Legislature drafted ORS 431A.260 to provide, as it must, that toy manufacturers “are exempt” from the statute if it conflicts with federal law. This exemption, of course, includes requirements under the FHSA and CPSA. There are no additional requirements; this exemption is automatic.

54. Under the express preemption provisions contained in both the FHSA and the CSPA, federal law is supreme, and it preempts Oregon law that is not “identical” to federal law, no

matter the intent of the Oregon legislature in passing laws governing the same products, and irrespective of any conditions, obligations, or other changes Oregon law may attempt to impose.

55. As recognized by Representative Alissa Keny-Guyer (one of the self-proclaimed “champions” of Oregon’s Toxic-Free Kids Act), the Oregon legislature intended to explicitly acknowledge that “Oregon can and will be preempted by federal laws in some cases. We included the language in Section 5 for these scenarios.” June 1, 2016 Letter from Rep. Keny-Guyer.

56. This “language” in Section 5 of the original act, codified at ORS 431A.260(3), explicitly recognizes that manufacturers of toys are “exempt” solely by the fact of their regulation under federal law:

Manufacturers are exempt from meeting the requirements of this section for children’s products described in subsection (1) of this section that contain high priority chemicals of concern for children’s health used in children’s products at levels that are at or below allowable levels for children’s products as established by the Consumer Product Safety Improvement Act of 2008, P.L. 110–314, 122 Stat. 3016, as in effect on the effective date of this 2015 Act.

57. There is, quite plainly, no additional requirement for a toy to be “exempt” under Oregon’s own statutory provision, which is consistent with how federal preemption works. If federal law governs, the toy is “exempt.” And, although ORS 431A.260(3) refers only to the CPSIA, the express-preemption provisions cited above apply to the entirety of the CPSA and the FHSA apply with equal force.

58. But the rule promulgated by the OHA — under this same statutory authority — disregards this simple, self-executing rule of federal preemption. Instead, the OHA’s new OAR 333-016-3015 adds an impermissible requirement that “in order to be exempt” from Oregon’s regulation, manufacturers must jump through several major hurdles created solely by the new OAR:

(2) A manufacturer is exempt from meeting the requirement of removal or substitution of a HPCCCH in a children’s product under ORS 431A.260 if one or more of the following is met:

(a) The children’s product contains a HPCCCH used in children’s products at levels that are at or below allowable levels for children’s products as established by the Consumer

Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, as in effect on July 27, 2015.

(b) A manufacturer is in compliance with a federal consumer product safety standard adopted under federal law that establishes allowable levels for children's products of a high priority chemical of concern for children's health used in children's products.

* * *

(4) In order to be exempt under one or more of the categories in section (2) of this rule a manufacturer must submit an exemption request and the fees specified in OAR 333-016-2080(1)(e) and provide to the Authority written supporting documentation, an electronic copy of the certificate of conformity, if available, that is issued by the applicable authority or an authorized designate, and any other supporting documentation that provides evidence that the children's product meets the applicable standards described in the applicable category including:

(a) For an exemption request under subsection (2)(a) of this rule, the citation for the section of the Consumer Product Safety Improvement Act of 2008, P.L. 110-314, 122 Stat. 3016, in effect on July 27, 2015, naming the HPCCCH.

(b) For an exemption request under subsection (2)(b) of this rule, a citation to the federal consumer product safety standard adopted under federal law that establishes an allowable level of a HPCCCH in children's products, specific to allowable levels of the HPCCCH in children's products.

59. In practice, these requirements present an onerous burden on toy manufacturers found only under Oregon's new rule. Several manufacturers have indicated that they would need to submit approximately 20 requests for each exemption sought (a separate exemption, with its separate \$1,500 fee, must be submitted for each chemical for which an exemption is sought). This burden alone amounts to \$30,000 per manufacturer.

60. Additionally, Plaintiffs estimate that it would take manufacturers about ten hours per product to gather and prepare information required under OAR 333-016-3015. At \$50 per hour, that is an additional \$500 for every product containing an HPCCCH "requiring" an exemption. And because OHA has altered the calculation methodology for substance concentration, additional testing is likely required, which adds another \$200 per product. These costs would be multiplied by about 30 products for small manufacturers and up to 15,000 products for larger ones, which results in estimated compliance costs of \$50,000 for the smallest manufacturers and up to as much as \$10 million for the largest ones.

61. Some manufacturers have indicated that this burden would result in abandoning sales of the subject toys and other children's products in Oregon, leaving Oregon's consumers to black-market sellers and counterfeiters that play by none of the rules, which endangers children in exactly the way the Toxic-Free Kids Act was passed to prevent.

62. These additional burdens cannot survive preemption under federal law. Under the express preemption provisions in the FHSA and the CSPA, Oregon's requirement in ORS 431A.260 mandating the "substitution or removal" of HPCCHs in children's toys under Oregon's standards is preempted by federal law regulating those same products, chemicals, and standards. Accordingly, OHA's attempt, under OAR 333-016-3015(4), to force manufacturers to pay a fee and submit a "by your leave" request to be exempt is preempted and made void under conflicting federal law.

COUNT 2

DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

OAR 333-016-3015

63. Plaintiffs reallege paragraphs 1-62.

64. Additionally, the OHA's attempt to impose new requirements to be exempt from Oregon's conflicting standards runs afoul of ORS 183.332, which requires the OHA to "attempt to adopt rules that correspond with equivalent federal laws and rules."

65. The new exemption requirements fail this test. They do not "correspond" to federal preemption laws, they contradict them.

66. Apart from the federal preemption, the requirements of OAR 333-016-3015(4) impermissibly add burdens that ORS 431A.260 omits.

67. OHA has exceeded its authority in drafting the new requirements found in OAR 333-016-3015 but missing from ORS 431A.260. Under ORS 413.042, which provides OHA's authority to create rules for administering the Toxic-Free Kids Act, "the Director of the Oregon Health Authority may adopt rules necessary for the administration of the laws that the Oregon Health Authority is charged with administering."

68. As pertinent here, the “law” that the OHA is “charged with administering” is ORS 431A.260. As discussed above, this statute acknowledges, as it must under the federal preemption doctrine, that a toy manufacturer is “exempt” from the mandates of ORS 431A.260 if the statute’s standards and obligations conflict with federal law.

69. As drafted by the Oregon Legislature, this exemption is automatically applicable simply by the existence of a conflict with federal law — just as the federal preemption doctrine requires.

70. But OAR 333-016-3015, by simple administrative fiat, pretends to add burdensome filing-fee, testing, and paperwork requirements, which is exactly the usurpation of power that the Oregon Supreme Court has prohibited.

71. A useful foil demonstrating the OHA’s fault here may be seen in another section of the Toxic-Free Kids Act, ORS 431A.258.

72. Under this statute, the Oregon Legislature expressly provided for the manner in which a toy manufacturer could seek an “exemption” from the statute’s notice requirements. ORS 431A.258(5)(a) (listing requirements for the application for exemption). This statutory requirement is then replicated in the rule administering this statute, ORS 333-016-2070(3).

73. The lack of parallel statutory authority in ORS 333-016-3015 demonstrates that OHA’s new requirements do not *administer* ORS 431A.260 — they *conflict* with it. Because ORS 431A.260 does not include the new burdensome requirements added by OAR 333-016-3015, the OHA’s new rule impermissibly exceeds what is explicitly “necessary” under the statute.

74. Plaintiffs are entitled to a declaration that the additional “exemption” provisions in OAR 333-016-3015 are beyond the OHA’s statutory authority, are preempted by federal law, and, for the same reasons, this Court should enjoin Defendants from enforcing these preempted provisions.

COUNT 3

DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

ORS 431A.258 and OAR 333-016-2060

75. Plaintiffs reallege paragraphs 1-46.

76. Oregon and federal law share the same commonsense and admirable goalpost: to protect children by identifying and banning children’s toys with chemicals that harm the children playing with them.

77. Under the FHSA, a “banned hazardous substance” means “any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance *in such manner as to be susceptible of access by a child* to whom such toy or other article is entrusted.” 15 U.S.C. § 1261(1)(1) (emphasis added); 16 CFR § 1500.3 (same).

78. This federal choice to test for, measure, and ban only “accessible” chemicals in children’s toys preempts Oregon’s ORS 431A.258 and OAR 333-016-2060, which require toy manufacturers to more broadly test, report, and ban chemicals in “component parts” of toys, even if those chemicals are not “accessible” under the FHSA or CPSA and do not harm the children using those toys.

79. Federal law places exacting limits on potentially hazardous chemicals and requires an extensive process for manufacturers to identify, test for, measure, and keep those toys (and chemicals) off toy-store shelves.

80. Throughout federal law on this subject, the U.S. Congress and its federal authorities recognize and require that only “accessible” chemicals are subject to testing, measurement, regulation, and, for toys exceeding these limits, banning:

Under the Federal Hazardous Substances Act (FHSA), products that are toxic or irritants and that may cause substantial injury or illness *under reasonably foreseeable conditions of handling or use*, including reasonably foreseeable ingestion by children, are “hazardous substances.” 15 U.S.C. 1261(f)(1). ... A toy or other article intended for use by children *that contains an accessible and harmful amount of a hazardous chemical* is banned. 15 U.S.C. § 1261(q)(1)(A).” 16 CFR § 1500.231(c)(1) (emphasis added).

81. The two cited statutes in this rule further demonstrate the intention, under federal law, to mandate testing and banning of chemicals only if they are “accessible” in the sense of being able to harm children “under reasonably foreseeable conditions of handling or use.”

82. The term “hazardous substance” means, “Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or *as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.*” 15 U.S.C. § 1261(f)(1)(A) (emphasis added).

83. And the term “banned hazardous substance” means “any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance *in such manner as to be susceptible of access by a child* to whom such toy or other article is entrusted.” 15 U.S.C. § 1261(q)(1)(A) (emphasis added).

84. Federal law purposely and explicitly exempts chemicals from testing, measurement, and banning regulations that are not “accessible” to children, or, stated differently, chemicals that do not present a risk of harm from the “customary or reasonably foreseeable handling or use” by children.

85. ORS 431A.258 and OAR 333-016-2060 obliterate this distinction, focusing instead on the “component part” or “unit” of a toy and requiring manufacturers (a) to test every “high priority” chemical in every “component part” of a toy, (b) to notify the OHA about those chemicals, and (c) then to remove or substitute them, or (d) stop selling the toy in Oregon altogether. *See* OAR 333-016-2060(5) (requiring manufacturers to determine and provide “notice” to the OHA regarding, among other things, the “amount of the chemical used in each unit” (which also means a “component part”) of a children’s toy, without regard to whether that chemical presents any risk of actual exposure and danger to a child); OAR 333-016-3010(1) (requiring manufacturers to “remove or make substitution” of chemicals in a defined subset of children’s products,

without regard to whether those chemicals are “accessible” or otherwise present an actual risk of harm to children).

86. Requiring manufacturers to determine the “amount of the chemical” present even in component parts that are not “accessible” to a child disrupts the very uniformity that a federal scheme of regulation was explicitly intended to provide. *See* 15 U.S.C. § 2051(b)(3) (declaring that the “purposes” of the CPSA include “to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations”); H.R. CONF. REP. 94-1022, 29, 1976 U.S.C.C.A.N. 1017, 1031 (“Even though the State or local requirement is characterized in different terms than the Federal requirement or may have different testing methods for determining compliance, so long as the Federal and State or local requirements deal with the same risk of injury associated with a product, the Federal requirement preempts a different State or local requirement.”).

87. For example, ASTM F963, a mandatory safety standard under the CPSA, includes detailed requirements “intended to reduce children’s exposure to heavy elements that may be contained in accessible toy substrate materials” in children’s toys. *Id.* § 4.3.5.2.

88. For these heavy metals, the solubility tests dictated by these federally mandated standards do not apply to toys or parts that are not “accessible” such that they do not present a risk to children: “Toys and parts of toys which, due to their inaccessibility, size, mass, function, or other characteristics, cannot be sucked, mouthed, or ingested are not subject to solubility testing requirements.” *Id.* *See also* § A11.10 (“Toys and toy components that are accessible to the child during play are subject to these requirements unless otherwise indicated.”). OHA’s recognition of testing methods ignores and conflicts with these requirements.

89. That is, federal law treats these heavy metals, which are potentially toxic and are included in Oregon’s list of HPCCCHs, as acceptably safe and beyond the solubility-testing and measurement requirements because the chemicals are not “accessible” to children under the specified circumstances.

90. Under these circumstances, federal law exempts any testing to determine the “amount” of these chemicals in a toy part that is not “accessible” to children — an exemption that Oregon’s novel statute and rule do not follow.

91. This difference, and the resulting burden on manufacturers only for toys sold in Oregon, destroys the “uniform” system of identification, testing, and banning erected by the complex, interlocking, and detailed system of federal laws, rules, and standards.

92. To protect its aim to provide this uniform system, the U.S. Congress included the express-preemption provisions in the CPSA and the FHSA, which requires that the federal laws preempt and negate any non-“identical” state laws, rules, and regulations.

93. This conflict and its resulting preemption are equally applicable, for another example, to federal regulation of phthalates.

94. As for other potentially hazardous or toxic chemicals in children’s toys, federal law exempts products from testing where the chemical is not “accessible” in a way that would present a risk to a child:

The CPSIA [Consumer Protection Safety Improvement Act] requires manufacturers of children’s products subject to a children’s product safety rule to certify that their children’s products comply with all applicable children’s product safety rules based on the results of third party tests. 15 U.S.C. 2063(a)(2). *Third party testing is only required for those components of children’s toys and child care articles that are accessible* and that could contain one or more of the prohibited phthalates. Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates. Fed. Register, Vol. 79, No. 249. (emphasis added).

95. OAR 333-016-2060 conflicts with this federal legal regime to regulating the content and composition of children’s products with phthalates in requiring manufactures to test every toy, and every “component part” of a toy, in order to determine and provide “notice” of the amount of phthalates in the toy. *See* OAR 333-016-2010 (defining “Children’s product” to include “Toys” but also any “component part of a product specified in paragraph (A) of this subsection,” which includes “toys”); OAR 333-016-2060 (requiring manufacturers to test, measure, and then provide notice for any “children’s product sold or offered for sale in this state that contains a HPCCCH,” which includes several phthalates).

96. Under the express-preemption provisions of the CSPA and the FHSA, Oregon’s non-“identical” regulation must fail because it is preempted by contrary federal laws, rules, and standards.

97. Plaintiffs are entitled to a declaration that the requirement to test components of toys that are not “accessible” to children under OAR 333-016-2060 are preempted by federal law, and, for the same reasons, this Court should enjoin Defendants from enforcing these preempted provisions.

PRAYER

WHEREFORE, Plaintiffs respectfully request that this Court:

1. On Count 1, declare that OAR 333-016-3015(4) is preempted by federal law, and is therefore void and unenforceable
2. On Count 2, declare that OAR 333-016-3015(4) is void because it exceeds the authority of the Oregon Health Authority to promulgate rules administering ORS 431A.260;
3. On Counts 1 and 2, enter a permanent injunction enjoining Defendant from taking any action to enforce OAR 333-016-3015(4), including any action that penalizes or restricts the distribution and sale of federally compliant, safe children’s products;
4. On Count 3, declare that ORS 431A.258 and OAR 333-016-2060 are preempted by federal law, and are therefore void and unenforceable;
5. On Count 3, enter a permanent injunction enjoining Defendant from taking any action to enforce ORS 431A.258 and OAR 333-016-2060;
6. Award to Plaintiffs reasonable attorney fees and costs as may be allowed under law; and
7. Award such other relief as this Court may deem just and appropriate.

Dated: December 6, 2021

s/ James T. McDermott

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